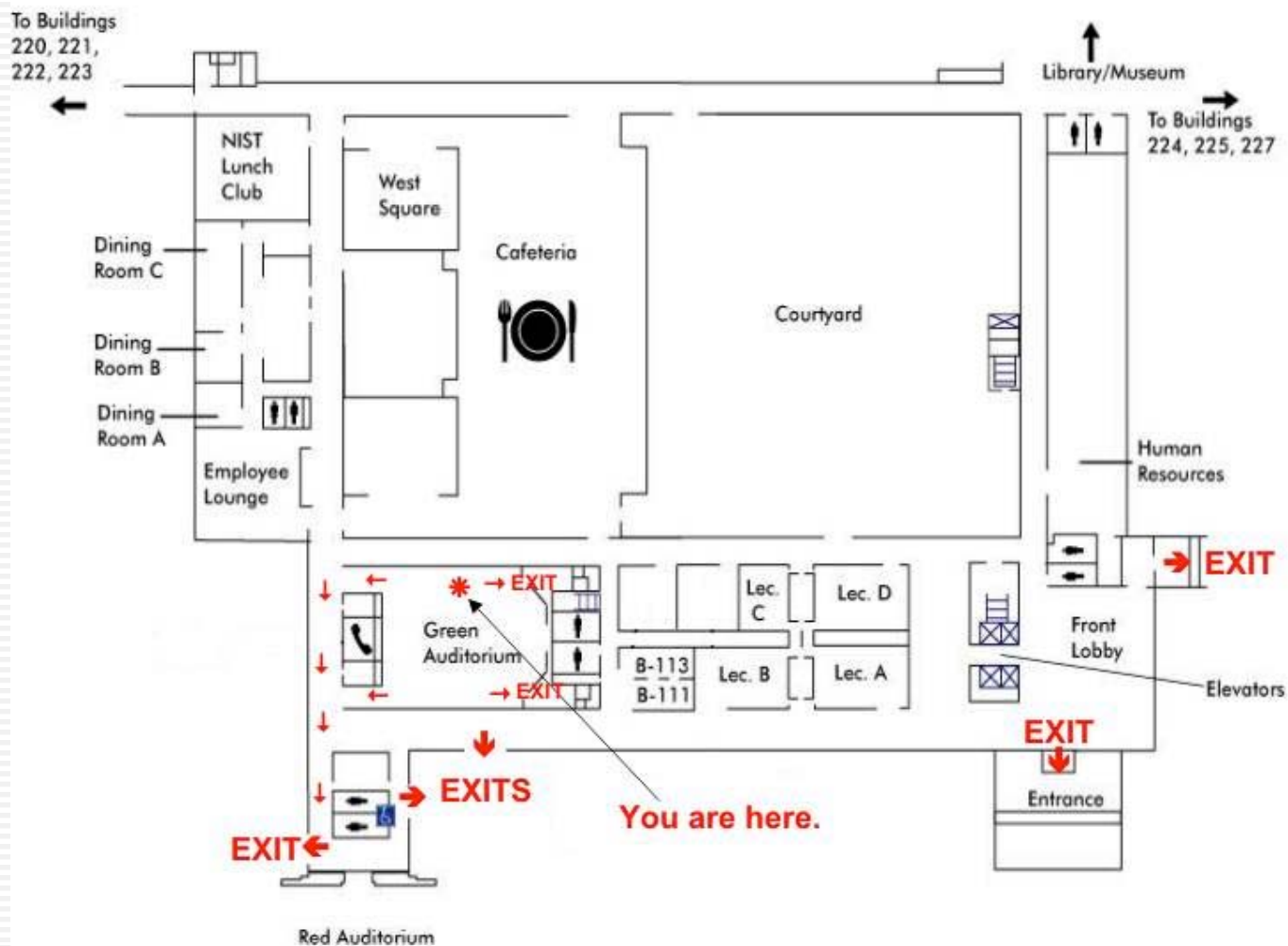# ERCC Workshop

Specifications for Universal External RNA Spike-In Controls

Green Auditorium Exits

Morning Agenda

- Welcome
  - Bill Koch, NIST/CSTL
- Introduction, History, Charge to the workshop
  - J. Warrington, Affymetrix
- FDA perspective
  - Steve Bauer, FDA CBER
- Document review
  - Access and Usability Requirements
    - Steve Bauer, FDA
  - Product Description
    - Patrick Giles

- Proposed Kit Configurations, Shelf life, Storage
  - Paul Wolber
- Coffee Break
- Review continues
  - Characteristics of Product Kits
    - Paul Wolber
  - Protocols
    - Mike Wilson
  - Testing
    - Laura Reid
- Lunch

Afternoon Agenda

- Review continues
  - Definitions and Assumptions for Measuring Acceptable Performance
    - Dave Gerhold
  - External RNA Control Quality Control by Quantitative Reverse Transcription-Polymerase Chain Reaction (RT-PCR)
    - Walter Koch
  - Comparison of External RNA Controls on Different Technology Platforms, Microarray and RT-PCR
    - Xiaoning Wu

- Coffee Break
- Panel Discussion – Technical Challenges and Gaps
- Interactive session: workplan and production specification development, resource requirements
- Workshop Summary and Next steps
  - J. Warrington/ Marc Salit
- Workshop concludes